Remarks

Claims 1-76 were pending in the subject application. By this Amendment, claims 1-3, 5, 6, 8, 9, 11, 13, 18, 19, 22-24, 29, 31-40, 42, 44, 45, 62, 64, 66, 69, 71, 72, and 74 have been amended, claims 4, 7, 10, 17, 25, 26, 30, 59-61, 75, and 76 have been cancelled, and new claims 77-79 have been added. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Claims 40-58 and 62-74 remain pending but withdrawn from consideration. It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of the applicants' agreement with or acquiescence in the Examiner's position. Accordingly, claims 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-39, 77-79 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The applicants acknowledge that claims 40-58 and 62-74 have been withdrawn from further consideration as being drawn to a non-elected invention. However, the applicants reserve the right to rejoinder of the non-elected process claims upon an indication of an allowable product claim in accordance with MPEP §821.04.

By this Amendment, claims 1-3, 5, 6, 8, 9, 11, 13, 18, 19, 22-24, 29, 31-40, 42, 44, 45, 62, 64, 66, 69, 71, 72, and 74 have been amended and claims 77-79 have been added. Support for these amendments can be found throughout the specification and claims as originally filed, and as specified below.

The specification is objected to for informalities for reciting "{001}", "(001)", "(002)", "(004)", "[001]", "(002)", and "(004)" at page 33 and elsewhere in the subject specification. The applicants respectfully submit that these are not informalities. Rather, they are art-recognized notations known as Miller indices, which are the most common convention used to describe directions, planes, and families of planes in crystal-lattice systems ([ ], ( ), { }, respectively), and referenced at page 33, lines 13-16, of the specification. Submitted herewith for the Examiner's consideration are the preface and sections 3.4.1 - 3.4.4 (pages 71-77) from the materials engineering text book entitled "The Science and Design of Engineering Materials" (Schaffer *et al.*, Second

Edition, 1999, McGraw Hill), which explains Miller index notation. Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Claims 1-39 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. The applicants respectfully submit that the claims are not indefinite, as they particularly point out and distinctly define the metes and bounds of the claimed subject matter to those of ordinary skill in the art. By this Amendment, the applicants have amended claim 1 to recite: a biomimetic organic/inorganic composite comprising a fluid-swellable, fibrous organic matrix comprising fibers and interstitial spaces; and an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces. Support for these amendments can be found, for example, at page 5, lines 11-19 and 28-31; page 6, lines 1-6; page 7, lines 14-19; page 8, lines 6-19; page 10, lines 28-30; page 11, lines 1-3; page 14, lines 1-6 and 15-16; page 15, lines 2-9; and page 22, lines 13-30, of the specification. The applicants address each aspect of this rejection in the paragraphs that follow.

By this Amendment, claims 4, 7, 10, 17, 25, 26, and 30 have been cancelled; thus, those aspects of the rejection involving the cancelled claims are moot.

As is clear from the subject specification, in the production method used by the inventors, the "liquid phase mineral precursor" (also referred to as the "polymer-induced liquid precursor" (PILP)) is a material that is transiently amorphous and is applied to the fluid-swellable, fibrous organic matrix and becomes intimately associated with it. The amorphous, liquid phase mineral precursor can then be permitted to harden and crystallize on the fluid-swellable organic matrix. In this way, the fluid-swellable fibrous organic matrix acts as a template for the liquid phase mineral precursor, influencing the structure of the inorganic mineral phase of the composite (see, for example, page 12, lines 13-16; page 13, lines 25-29; page 14, lines 13-18; page 39, lines 4-6; and claim 5 as filed). However, to add further clarity to the claims, claim 1 has been amended to remove the term "liquid phase mineral precursor". Claim 1 now recites that the inorganic mineral phase of the composite has an amorphous or crystalline structure. New claim 77 recites that the inorganic mineral phase has an amorphous structure. New claim 78 recites that the inorganic mineral phase has a crystalline structure.

The applicants respectfully submit that recitation of the term "fibrous matrix" provides clear antecedent basis for "fibers", particularly in light of the teachings of the specification; however, the applicants have amended claim 1 to affirmatively recite that the fibrous matrix comprises fibers, as recommended by the Examiner. New claim 79 specifies that the fibers are fibrils, as described, for example, at page 2, lines 4-7; page 6, lines 12-13; and page 13, lines 7-14, of the specification.

With respect to claim 5, the applicants respectfully submit that, in light of the specification, one or ordinary skill in the art would understand the term "non-faceted topography" to mean that crystals of the inorganic mineral phase lack facets (see page 13, lines 18-22; and page 14, lines 21-28). By this Amendment, the applicants have amended claim 5 to recite that the crystals of the inorganic mineral phase are non-faceted.

As indicated above in response to the objection to the specification, the notation "[001]" in claim 6 and similar notations throughout the specification and claims, are art-recognized as Miller indices, which are the most common convention used to describe directions, planes, and families of planes in crystal-lattice systems ([ ], ( ), { }, respectively). Their meaning is clear to those of ordinary skill in the art.

With respect to dependent claim 8, as indicated above, claim 1 has been amended to recite that the fluid-swellable, fibrous organic matrix comprises fibers and interstitial spaces. Thus, the meaning of claim 8 is clear. The applicants respectfully submit that the term "peptide nanofibers" is an art-recognized term, as demonstrated by the following publications, which are submitted herewith: Hartgerink *et al.*, *PNAS*, 2002, 99(8):5133-5138; Hong *et al.*, *Biomacromolecules*, 2003, 4(5):1433-1442; Wagner *et al.*, *PNAS*, 2005, 102(36):12656-12661; Davis *et al.*, 2005, 111:442-450; Tokoi *et al.*, *PNAS*, 2005, 102(24):8414-8419; and Ellis-Behnke *et al.*, *PNAS*, 2006, 103(13):5054-5059.

With respect to claims 9 and 14, the applicants submit that the term "surface-modified" is art-recognized. As taught at page 18, lines 8-11, of the specification, the fluid-swellable, fibrous matrix can be surface modified before, during, or after mineralization using any of a variety of means known in the art, such as plasma treatment, etching, ion implantation, radiation, electron beam, chemical functionalization, grafting, photopolymerization, adsorption, or combinations thereof.

With respect to claim 12, the recited collagen types 1-20 (I-XX) are known in the art, as demonstrated by the following publications, which are submitted herewith: Kadler *et al.*, *Biochem. J.*, 1996, 316:1-11; Badylak, *Cell & Developmental Biology*, 2002, 13:377-383; and Gelse *et al.*, *Advanced Drug Delivery Reviews*, 2003, 55:1531-1546. Page 1, first column, first paragraph, of the Kadler *et al.* publication, page 378, first column, last paragraph, of the Badylak publication, and the abstract and Table 1 of the Gelse *et al.* publication indicate that there are more than 20 different collagen types identified thus far.

With respect to claims 13 and 18, the applicants submit that the term "abutting fibrils" is clear in the view of the specification. As taught at page 14, lines 17-20 of the specification, the production method used by the inventors permits the liquid-phase mineral precursor to be drawn into the gaps and/or grooves of the collagen fibrils. The terms "gaps" and "grooves" are known in the field of biomineralization.

With respect to claim 19, the claim has been amended to recite that the one or more biologically active agents are on or within the composite. Support for this amendment can be found at pages 18-21 of the specification.

With respect to claim 20, the claim recites "substances used for the treatment, prevention, diagnosis, cure or mitigation of disease or illness". Thus, it is clear that the recited substance is the biologically active agent.

With respect to claims 22 and 23, independent claim 1 as currently amended provides a physical form for the recited inorganic mineral phase.

With respect to claim 31, the claim has been amended to replace the term "organic substrate" with "fluid-swellable, fibrous organic matrix", which has antecedent basis in claim 1.

With respect to claim 22, the claim has been amended to recite that the organic/inorganic composite further comprises cells seeded on the composite.

With respect to claim 35, the claim has been amended to replace the term "organic substrates" with "fluid-swellable, fibrous organic matrices", which has antecedent basis in claim 1.

The term "osteon-like structure" has been removed from claim 36.

With respect to claim 37, the elected claims no longer recite deposition of the inorganic mineral phase. Claim 1 makes clear that the inorganic mineral phase has an amorphous and

crystalline structure and coats and infiltrates each fiber of the fluid-swellable, fibrous organic matrix. Claim 37 makes clear that the composite further comprises an adhesive layer between each fluid-swellable, fibrous organic matrix.

Claim 38 has been amended to recite that the fibers of the plurality of fluid-swellable, fibrous organic matrices are oriented in parallel. Claim 39 has been amended to recite that the fibers of each of the fluid-swellable, fibrous matrices are oriented in parallel, and the fibers of adjacent fluid-swellable, fibrous organic matrices are not parallel with each other (*i.e.*, in an alternating fashion, as described at page 38, lines 30-31; page 39, lines 1-13; and Figures 23A-23C of the specification.

As the Examiner is aware, the essential inquiry pertaining to the requirement of definiteness under §112, second paragraph, is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (a) the content of the particular application disclosure; (b) the teachings of the prior art; and (c) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP §2173.02.

The claims set forth subject matter that the applicants regard as the invention and particularly point out and distinctively define the metes and bounds of the subject matter embraced by the claims, which is all that is required under 35 U.S.C. §112, second paragraph. The test for definiteness under 35 U.S.C. §112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576; 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-5, 7, 8, 11-13, 15, 24-29, and 31 have been rejected under 35 U.S.C. §102(b) as being anticipated by Olszta R9 ("Biomimetic mineralization of type-I collagen" presented at the 7th Int. Conf.—The Chemistry and Biology of Mineralized Tissues, November 4-9, 2001, Sawgrass, FL) or Olszta R11 ("Biomimetic mineralization of type-I collagen" presented at UEF Biomimetic Engineering Conference, March 3-7, 2002, Destin, FL) or Olszta R27 ("Biomimetic Mineralization of Collagen for Nanostructured Composites" poster materials, June 2001, Department of Materials Science and Engineering, University of Florida, Gordon Research Conference). In addition, claims

6, 16, 17, and 18 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, R27 in view of Silver *et al.* (U.S. Patent No. 5,532,217). Further, claims 9, 10, and 14 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Rhee *et al.* (U.S. Patent No. 5,800,541). Also, claims 19-21 and 23 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Liu (U.S. Patent No. 6,300,315). Claim 22 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27, in view of Liu and further in view of Rhee *et al.* Claim 30 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Brown *et al.* (U.S. Patent No. 6,201,039). Claims 32, 33, 35, and 36 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Connelly *et al.* (U.S. Patent No. 6,995,013). Claims 34 and 37-39 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Song *et al.* (U.S. Patent No. 5,418,222).

Each of the prior art rejections under 35 U.S.C. §102(b) and §103(a) rely on the above-referenced Olszta R9, R11, or R27 presentations. The applicants respectfully traverse these grounds for rejection and submit that the Patent Office has not met its burden to establish that the cited presentations are public disclosures. Moreover, the Olszta R9, R11, or R27 presentations are not prior art to the claimed invention. As the Examiner is undoubtedly aware, the requirements for authorship and inventorship are not the same. The inventorship of the claimed invention and the authorship of the Olszta R9, R11, and R27 presentations differ in that, although Drs. Elliot P. Douglas, Sivakumar Munisamy, and Donna L. Wheeler are inventors on the subject application, they are not co-authors of the Olszta R9, R11, or R27 presentations. Thus, Dr. Matthew J. Olszta and Dr. Laurie B. Gower are co-authors of the Olszta R9, R11, or R27 presentations and are inventors on the subject application.

Submitted herewith is a Declaration under 37 C.F.R. §1.132 by Dr. Gower for the Examiner's consideration (referred to herein as the Gower Declaration). Dr. Gower explains in her Declaration that Dr. Douglas, Dr. Olszta, and Dr. Gower contributed to the conception of mineralizing a collagen matrix using the process of the invention, resulting in the organic/inorganic composite of the invention (*e.g.*, claim 1). The experiments described in the Olszta R9, Olszta R11, and Olszta R27 presentations, which were carried out by Dr. Olszta and Dr. Gower, confirmed that the process

conceived by Dr. Douglas, Dr. Olszta, and Dr. Gower worked for its intended purpose. As explained by Dr. Gower, "Dr. Douglas did not participate in the presentations and was not directly involved in carrying out the experiments described in the presentations; however, it is only for these reasons that he was not included as a co-author of the Olszta R9, Olszta R11, and Olszta R27 presentations."

As the Examiner is aware, the person or persons who are the first to conceive the invention as claimed in a patent application are the inventors. Conception can be defined as "the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice". *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 87 (Fed Cir. 1986) quoting 1 Robinson on Patents 532 (1890); *Coleman v. Dines*, 224 USPQ 857, 862 (Fed. Cir. 1985). Joint inventors must have "some quantum of collaboration or connection" and contribute to at least one element of the claims. However, inventors may file jointly even if they did not work together at the same location at the same time, or each did not make the same kind or amount of contribution, or each did not make a contribution to the subject matter of every claim of the patent. *Monsanto Co. v. Kamp*, 154 USPQ 259, 262 (D.D.C. 1967).

As explained in the Gower Declaration, Dr. Munisamy demonstrated that a collagen matrix could be mineralized by the process of the invention, using a calcium phosphate precursor phase, which was formed by combining calcium chloride and a combination of polymers to form an aqueous solution, and reacting the aqueous solution with ammonium phosphate vapor, resulting in a collagen matrix mineralized with calcium phosphate (*e.g.*, claim 15). This procedure is not described in the Olszta R9, Olszta R11, and Olszta R27 presentations. Therefore, Dr. Munisamy was not included as a co-author of the Olszta R9, Olszta R11, and Olszta R27 presentations.

Furthermore, as explained in the Gower Declaration, Dr. Wheeler contributed to that aspect of the invention involving the incorporation of proteins, such as growth factors, to the composite of the invention (*e.g.*, claims 20, 32, and 33). This aspect of the invention is not described in the Olszta R9, Olszta R11, and Olszta R27 presentations.

The subject matter pertaining to the claimed invention that is described within the Olszta R9, Olszta R11, and Olszta R27 presentations was invented by the named co-inventors, *i.e.*, Laurie B. Gower, Matthew J. Olszta, and Elliot P. Douglas. Therefore, the Olszta R9, Olszta R11, and Olszta

R27 presentations represent the inventors' own disclosure of their invention published less than one year prior to the filing date of the subject application.

"[O]ne's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar." *In re Facius,* 161 USPQ 294, 301 (CCPA 1969); and MPEP §715.01(c). Therefore, under the authority of *In re Facius*, the disclosure contained in the Olszta R9, R11, or R27 presentations cannot be used as a reference against the applicants' claimed invention.

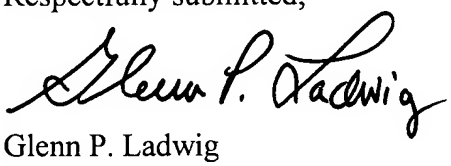
The other cited references (Silver *et al.*, Rhee *et al.*, Liu, Brown *et al.*, and Song *et al.*) do not teach or suggest the applicants' claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) and §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Petition and Fee for Extension of Time
Declaration under 37 C.F.R. §1.132 by Dr. Gower
Preface and Pages 71-77 from the "The Science and Design of Engineering Materials"
Hartgerink *et al.*, *PNAS*, 2002, 99(8):5133-5138
Hong *et al.*, *Biomacromolecules*, 2003, 4(5):1433-1442
Wagner *et al.*, *PNAS*, 2005, 102(36):12656-12661
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